



SACRAMENTO MEDICAL FOUNDATION | Blood Centers

2694 '99 SEP 14 P2:20

September 10, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: **Docket Number 98D-0814**

Dear Sir:

This letter is a follow-up to my previous one of July 21, 1999 concerning the above-referenced Docket Number. While I appreciate that the comment period is over for providing input on the HCV 1.0 Lookback Draft Guidance document, I would like to bring two points to your attention.

First: Many centers had access to the RIBA 1.0 in looking for "confirmation" of repeatedly reactive donor samples with anti-HCV by the EIA 1.0. If the RIBA 1.0 were negative, this should not trigger a lookback, even if the EIA had an S/N ratio of 2.5 or greater. On the other hand, if the RIBA 1.0 were indeterminate or positive, i.e., one or both bands were present, the lookback should be carried out.

Second: If the blood center or hospital has evidence that a prior transfusion, especially one immediately preceding an HCV 1.0 repeatedly reactive donation, was not infectious for a recipient, then all prior donations should not be investigated for potential infectiousness. Some centers, such as our own, conducted such research studies; we carried out HCV testing, using the 1.0 and 2.0 EIA tests, the RIBA 2.0 test, and the polymerase chain reaction for HCV RNA, on such transfused recipients who enrolled in the study. Thus, if infection with HCV did not occur with the donation collected immediately prior to the repeatedly reactive "trigger" one by EIA HCV 1.0 testing, it would be extremely unlikely that donations prior to that would be infectious. Therefore, it would seem logical, and appropriate, to truncate HCV lookback based upon such evidence.

Thank you for your consideration of these follow-up comments.

Sincerely,

Paul V. Holland, MD
Medical Director/Chief Executive Officer

PVH:rc 290.99

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Q8D-0814

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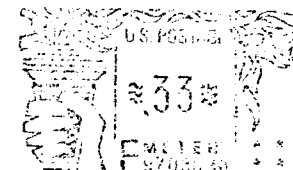
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